

increasing the size of the opening in the drape during said surgically operating step; and]

25 locating the selected portion of the body by referencing the body relative to the indicia on the drape in a manner corresponding to said referencing step of the radiographic image [, said locating step comprising identifying the selected direction and depth through the body by referencing the body relative to the indicia on the drape identified in said referencing step of the radiographic image] ;

locating the selected direction by orienting a beam of light to coincide with the selected direction and to intersect the reference indicia;

30 positioning a surgical member adjacent to the drape such that the surgical member is intersected by the beam of light; and

translating the surgical member toward the drape such that the surgical member is continuously intersected by the beam of light, said translating step being over a sufficient length such that the surgical member passes through an opening in the drape and an  
35 incision in the body to become lodged within a portion of the body intersected by the selected direction.

#### REMARKS

Entry of the foregoing amendments is requested. Attached hereto as Exhibit 1 are substitute pages entitled "Claims 1 to 29 – Present Amendments Included" that contain claims 1, 11, 15, 16, and 22 to 27, amended as requested herein, and other pending claims 2, 5 to 8, 12, 17, 18, 20, 21, 28 and 29. Exhibit 1 does not include claims 3, 4, 9, 10, 13, 14 and 19, which have been cancelled herein.

Reconsideration of the above-identified application comprising claims 1, 2, 5 to 8, 11, 12, 15 to 18, and 20 to 29, upon entry of the foregoing amendments, in view of the following remarks is hereby requested.

Claims 1 to 27 have been rejected. Claims 28 and 29 have been allowed. Office Action, Office Action Summary, ¶¶ 5, 6, p. 3, ¶ 4.

Legal standards – 35 U.S.C. § 103

The burden of proof in the examination of a patent application is initially on the examiner. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). If the examiner does not establish “a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent.” *Id.*

To establish a *prima facie* case of obviousness, the prior art must (i) contain a “suggestion” of the claimed invention, and (ii) reveal “a reasonable expectation of success”, in practicing the invention of the patent application. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

The “suggestion” and “reasonable expectation of success” must be demonstrated without reliance upon applicant’s disclosure. *Vaeck*, 947 F.2d at 493. This is important to avoid “the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher’ ... [I]dentification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness, ... there must be some motivation, suggestion or teaching of the desirability of” combining or modifying the prior art to make the invention of the patent application. *In re Kotzab*, 217 F.3d 1365, 1369-70 (Fed. Cir. 2000).

If a *prima facie* case of obviousness is established by the examiner, then the applicant must submit evidence or argument to demonstrate patentability. *Oetiker*, 977 F.2d at 1445. Patentability is then determined “by a preponderance of evidence with due consideration to persuasiveness of argument”. *Id.*

Claims 1 to 10 (35 U.S.C. § 103)

Claims 1 to 10 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,260,985 (Mosby) in view of “3MiobanDrapes (1987)”. Office Action, p. 2 to 3, ¶ 3.

Claim 1, as amended herein, defines an antimicrobial drape having indicia affixed to a portion thereof. The indicia are defined as comprising coordinates which are rectilinear and orthogonal. This type of indicia are important because they enable the targeting benefits of the drape to be achieved on flat and cylindrical surfaces as illustrated in Figs. 1, 6 to 8, 13, 14, 17 to 20, 26, 27, 29 and 30 of the above-identified application.

Mosby fails to disclose or suggest indicia comprising coordinates which are rectilinear and orthogonal. In contrast, Mosby discloses polar coordinates applied to a paraboloid-shaped body. Mosby in no way discloses or suggests the polar coordinates being applied to any surface other than a protrusion or bulge. This limitation of Mosby results from the “localization” function of Mosby, for which the polar coordinates are used, to also require a “box-like apparatus” which covers the protrusion/bulge such that the protrusion/bulge occupies the interior of the “box-like apparatus” (col. 2, lines 10 to 35, col. 4, lines 11 to 41, col. 7, lines 43 to 45, col. 10, lines 12 to 14). Mosby nowhere discloses or suggests using the grid for localization without the “box-like apparatus” (e.g., col. 3, lines 9 to 14). Therefore, there is no disclosure or suggestion of using the grid of Mosby with a surface other than a protrusion or bulge.

show no exclusion of a box-like apparatus

Accordingly, Mosby fails to disclose or suggest the rectilinear and orthogonal coordinates specified by claim 1, as amended herein, since Mosby fails to disclose or suggest use of its grid with surfaces to which rectilinear and orthogonal coordinates are suited. Examples of such surfaces (to which rectilinear and orthogonal coordinates are suited) are shown in Figs. 1, 6 to 8, 13, 14, 17 to 20, 26, 27, 29 and 30 of the above-identified application. If bodies having such surfaces were attempted to be targeted,

according to the above-identified application, using the polar coordinates of Mosby, such targeting, if even possible, would be much less effective than if such targeting was performed using the rectilinear and orthogonal coordinates defined by claim 1. The rectilinear and orthogonal coordinates are disclosed in the above-identified application, as originally filed, in Figs. 1, 4 and 5, and on p. 21, lines 14 to 23.

Moreover, the Office Action does not appear to contain any specific reference to prior art which discloses or renders obvious rectilinear and orthogonal coordinates as specified by claim 1, as amended herein. Rectilinear and orthogonal coordinates were specified by claim 4 which was pending in the above-identified application when the Office Action issued. Office Action, "Office Action Summary", ¶ 4, 6, p. 2, ¶ 3. Claim 4 has been cancelled herein. The failure of the Office Action to specifically address the rectilinear and orthogonal coordinates specified in then-pending claim 4, and specified in claim 1, as amended herein, **in and of itself** is respectfully submitted as resulting in the Office Action failing to establish a *prima facie* case of unpatentability for claim 1.

Moreover, it is submitted that, in view the deficiencies of Mosby discussed in the foregoing, the Office Action has not established a *prima facie* case of unpatentability for claim 1. And, assuming *arguendo* that a *prima facie* case has been established, it is believed that, in view of the foregoing, the Office Action has not established unpatentability of this claim by a preponderance of the evidence. *Oetiker*, 977 F.2d at 1445. Accordingly, it is believed that the rejection of claim 1 should be withdrawn, and such action is requested.

Claims 2, and 5 to 8 depend directly or indirectly from claim 1. Accordingly, it is believed that the rejection of these dependent claims should be withdrawn for the same reasons as for claim 1, and such action is requested.

Claims 3, 4, 9 and 10 have been cancelled herein.

Claims 11, 12 (35 U.S.C. § 103)

Claims 11 and 12 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,260,985 (Mosby) in view of “3MiobanDrapes (1987)”. Office Action, p. 2 to 3, ¶ 3.

Claim 11, as amended herein, defines an antimicrobial drape formed of expandable material and sized to have an internal volume which is less than the volume of the elongate body enabling the drape to be shrink-fitted onto the body. Such shrink-fitting is important because it enables the drape, and the indicia, to be fixed to the body for targeting, without requiring adhesive or the like for such fixing. Shrink-fitting of the drape onto the body is disclosed in the above-identified application, as originally filed, on p. 26, lines 1 to 6, and p. 37, line 27 to p. 38, line 3.

The drape formed of expandable material and sized to enable the shrink-fitting defined by claim 11 is not disclosed or suggested by Mosby. In contrast, Mosby discloses “a flat transparent adhesive sheet of material with imprinted radiopaque and visible grid lines” (col. 5, lines 7 to 12). Additionally, Mosby discloses that “the conforming grid, g, adheres and conforms to the outline of subject breast” (col. 6, lines 44 to 47).

The Office Action does not appear to contain any specific reference to prior art which discloses or renders obvious the drape formed of expandable material and sized to enable the shrink-fitting as defined by claim 11. Such a shrink-fitting structure was specified by claim 14 which was pending in the above-identified application when the Office Action issued. Office Action, “Office Action Summary”, ¶ 4, 6, p. 2, ¶ 3. Claim 14 has been cancelled herein. The failure of the Office Action to specifically address the shrink-fitting structure specified in then-pending claim 14, and specified in claim 11, as

amended herein, **in and of itself** is respectfully submitted as resulting in the Office Action failing to establish a *prima facie* case of unpatentability for claim 11.

Moreover, it is submitted that, in view the deficiencies of Mosby discussed in the foregoing, the Office Action has not established a *prima facie* case of unpatentability for claim 11. And, assuming *arguendo* that a *prima facie* case has been established, it is believed that, in view of the foregoing, the Office Action has not established unpatentability of this claim by a preponderance of the evidence. *Oetiker*, 977 F.2d at 1445. Accordingly, it is believed that the rejection of claim 11 should be withdrawn, and such action is requested.

Claims 12 and 15 depend from claim 11. Accordingly, it is believed that the rejection of these dependent claims should be withdrawn for the same reasons as for claim 11, and such action is requested.

Claims 13 and 14 have been cancelled herein.

Claims 16 to 18, 20, 21 (35 U.S.C. § 103)

Claims 16 to 18, 20 and 21 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,260,985 (Mosby) in view of “3MiobanDrapes (1987)”. Office Action, p. 2 to 3, ¶ 3.

Claim 16, as amended herein, specifies a conical antimicrobial drape having sufficient flexibility to conform to the outer surface of a conical body. The drape has a longitudinally extending radial cutout which increases the flexibility of the drape. The cutout thereby facilitates conformance of the drape with the conical body and enables the drape to be applied to conical bodies having different sizes. The cutout is disclosed in the above-identified application, as originally filed, in Figs. 31 and 32, and on p. 27, lines 6 to 9, and p. 38, lines 3 to 7.

In contrast, Mosby does not disclose or suggest a radial cutout, as defined by claim 16. The range of sizes of a human breast to which the “conforming grid sheet” of Mosby may be applied is therefore limited.

The Office Action does not appear to contain any specific reference to prior art which discloses or renders obvious the conical drape having a radial cutout as defined by claim 16. Such a radial cutout was specified by claim 19 which was pending in the above-identified application when the Office Action issued. Office Action, “Office Action Summary”, ¶ 4, 6, p. 2, ¶ 3. Claim 19 has been cancelled herein. The failure of the Office Action to specifically address the radial cutout specified in then-pending claim 19, and specified in claim 16, as amended herein, **in and of itself** is respectfully submitted as resulting in the Office Action failing to establish a *prima facie* case of unpatentability for claim 16.

Moreover, it is submitted that, in view the deficiencies of Mosby discussed in the foregoing, the Office Action has not established a *prima facie* case of unpatentability for claim 16. And, assuming *arguendo* that a *prima facie* case has been established, it is believed that, in view of the foregoing, the Office Action has not established unpatentability of this claim by a preponderance of the evidence. *Oetiker*, 977 F.2d at 1445. Accordingly, it is believed that the rejection of claim 16 should be withdrawn, and such action is requested.

Claims 17, 18, 20 and 21 depend, directly or indirectly, from claim 16. Accordingly, it is believed that the rejection of these dependent claims should be withdrawn for the same reasons as for claim 16, and such action is requested.

Claims 22 to 26 (35 U.S.C. § 103)

Claims 22 to 26 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,260,985 (Mosby) in view of “3MiobanDrapes (1987)”. Office Action, p. 2 to 3, ¶ 3.

Claims 22 and 26, as amended herein, define a method for correlating a selected portion within a body to a radiographic image of the body. The methods specify that formation of the radiographic image be followed by referencing and locating. Next, sufficiently unobstructed access is provided to the indicia region of the drape to enable positioning by the hand of the operator adjacent to the indicia region, and a surgical incision is made through the indicia region. Following this, imaging, referencing and locating is again performed. Such unobstructed access to the indicia region of the drape is disclosed in the above-identified application, as originally filed, in Figs. 1, 8, 17 to 20, 27, 30 and 31. The subsequent imaging, referencing and locating is disclosed in the above-identified application, as originally filed, on p. 1, lines 7 to 13, p. 2, lines 10 to 13, p. 6, lines 1 to 19, and p. 35, line 26 to p. 36, line 13.

The steps of referencing and locating, both before and after the surgical incision, defined by claims 22 and 26, are important because it provides information regarding the location of the incision contemporaneous with the surgery. This facilitates accurate placement of the incision. Also important is the provision of unobstructed access to the indicia region since this facilitates locating and making the incision since the hand of the operator may be positioned adjacent to the incision during the making thereof.

In contrast, Mosby discloses insertion of a control stylet and localization needle through a “box-like apparatus” which covers the protrusion/bulge such that the protrusion/bulge occupies the interior of the “box-like apparatus” (col. 2, lines 10 to 35, col. 4, lines 11 to 41). The “box-like apparatus” renders the disclosure of Mosby



significantly different from the methods defined by claims 22 and 26 because, in Mosby, the “box-like apparatus” is **required** for positioning the control stylet and localization needle, and the “box-like apparatus” prevents the hand of the operator from being positioned adjacent to the “conforming grid sheet” (*cf.*, col. 1, lines 28 to 66, col. 3, lines 9 to 15). The “box-like apparatus” thereby presents an obstruction which severely limits the variety of surgical procedures which may be performed contemporaneously with the taking of the X-rays (*cf.* col. 3, line 11 to 14). Accordingly, Mosby does not disclose or suggest the methods defined by claims 22 and 26.

Moreover, claim 26 defines the additional step of inserting an implant through the surgical incision before the second imaging, referencing and locating steps. Such an implant is disclosed in the above-identified application, as originally filed, on p. 11, lines 14 to 21, 29 to 32, p. 36, lines 15 to 16, p. 37, lines 7 to 8, 23, and p. 39, lines 6 to 17. Insertion of an implant through the surgical incision would be obstructed by the “box-like apparatus” of Mosby. Accordingly, for this additional reason, Mosby does not disclose or suggest the method defined by claim 26.

It is submitted that, in view the deficiencies of Mosby discussed in the foregoing, the Office Action has not established a *prima facie* case of unpatentability for claims 22 and 26. And, assuming *arguendo* that a *prima facie* case has been established, it is believed that, in view of the foregoing, the Office Action has not established unpatentability of these claims by a preponderance of the evidence. *Oetiker*, 977 F.2d at 1445. Accordingly, it is believed that the rejections of claims 22 and 26 should be withdrawn, and such action is requested.

Claims 23 to 25 depend, directly or indirectly, from claim 22. Accordingly, it is believed that the rejection of these dependent claims should be withdrawn for the same reasons as for claim 22, and such action is requested.

Claim 27 (35 U.S.C. § 103)

Claim 27 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,260,985 (Mosby) in view of “3MiobanDrapes (1987)”. Office Action, p. 2 to 3, ¶ 3.

Claim 27, as amended herein, defines a method for referencing a selected direction through the body and using a reference indicia on the drape to identify the direction. Also, the method includes locating the selected direction on the body by orienting a beam of light to coincide with the selected direction and intersect the reference indicia. Further, a surgical member is positioned adjacent to the drape such that the surgical member is intersected by the beam of light. The surgical member is then translated toward the drape such that the surgical member is continuously intersected by the beam of light. This translation is over a sufficient length such that the surgical member passes through an opening in the drape and an incision in the body to become lodged within a portion of the body intersected by the selected direction. The locating of the selected direction by orienting a beam of light is disclosed in the above-identified application, as originally filed, on p. 11, lines 6 to 27, p. 31, lines 3 to 11, and p. 39, line 29 to p. 40, line 1.

Claim 27 thereby provides a method for defining a selected direction through a body, which may be referred to as a “surgical corridor”. The method further provides for inserting a surgical member, such as an implant, through the body along the selected direction to a location within the body along the selected direction. This enables control over the precise portions of the body through which the surgical member is translated.

Mosby does not disclose or suggest translating a surgical member through a body in a specific direction relative to the body. Accordingly, Mosby does not disclose or suggest the method defined by claim 27.

It is submitted that, in view the deficiencies of Mosby discussed in the foregoing, the Office Action has not established a *prima facie* case of unpatentability for claim 27. And, assuming *arguendo* that a *prima facie* case has been established, it is believed that, in view of the foregoing, the Office Action has not established unpatentability of these claims by a preponderance of the evidence. *Oetiker*, 977 F.2d at 1445. Accordingly, it is believed that the rejection of claim 27 should be withdrawn, and such action is requested.

Supplemental Information Disclosure Statement

A “Supplemental Information Disclosure Statement” (the “Supp. IDS”) was mailed to the USPTO by Applicant on November 21, 2001. The “Supp. IDS” contained a Form PTO/SB/08A including 2 pages. The Office Action received by Applicant contained p. 1, but not p. 2, of the Form PTO/SB/08A (the Form PTO/SB/08A attached to the Office Action is identified as “Sheet 1 of 2” thereby indicating a second page). Applicant requests a copy of the “Sheet 2 of 2” of the Form PTO/SB/08A contained in the “Supp. IDS” initialed by the USPTO Examiner to indicate entry and consideration of the documents listed therein.

Conclusion

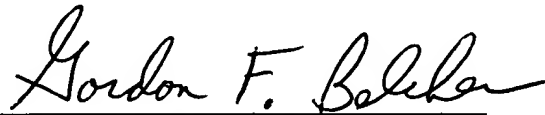
The foregoing is submitted as being fully responsive to the Office Action including the rejections contained therein. Accordingly, the above-identified application, presently containing claims 1, 2, 5 to 8, 11, 12, 15 to 18, and 20 to 29, is submitted as being allowable and allowance thereof is requested.

No fees are believed to be required for entry and consideration of the present “Amendment”. However, if any fees are required, please charge the Deposit Account No. 08-2776 of the below-identified firm for all required fees.

If the Examiner has any questions about the above, Applicant's Attorney Gordon F. Belcher is requested to be contacted at the below-identified telephone number. Additionally, please address all future correspondence to the below-identified address.

Please return the enclosed self-addressed postcard stamped by the USPTO to indicate timely receipt of the present "Amendment".

Respectfully submitted,



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Certificate of Mailing Under 37 C.F.R. § 1.8

I hereby certify that this paper entitled **AMENDMENT** and all attachments and enclosures referred to therein, namely, **Exhibit 1** (Claims 1 to 29 – Present Amendments Included) are being deposited with the United States Postal Service as first-class mail, postage prepaid, in an envelope addressed to:

Commissioner for Patents  
Washington, D.C. 20231

on April 16, 2002  
(Date of Deposit)

Rita Robkoff Akgun  
(Name of person making deposit)



(Signature)



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### Claims

The invention claimed is:

31 1. A surgical targeting system for adding an indicia image to a radiographic image of a body resulting from passage of image radiation through the body, said targeting system comprising:

5 an antimicrobial drape having an inner surface of sufficient flexibility to conform to at least a portion of an outer surface of the body, said drape being puncturable to provide access to the outer surface of the body, said drape being transparent to the imaging radiation;

10 an indicia affixed to a portion of said drape, said indicia comprising coordinates which are rectilinear and orthogonal, said indicia being opaque to the imaging radiation resulting in the indicia image corresponding to said indicia; and

a means for fixing said drape to the outer surface of the body such that said indicia provides a reference on the body for correlating portions of the body to the radiographic body image.

2. The surgical targeting system of claim 1 wherein said drape comprises plastic impregnated with iodophor.

5. The surgical targeting system of claim 1 wherein said fixing means comprises adhesive applied to said inner surface of said drape.

6. The surgical targeting system is claim 5 wherein said adhesive is applied continuously to the entire inner surface of said drape.

7. The surgical targeting system of claim 1 wherein said drape comprises a cylindrical portion.

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8. The surgical targeting system of claim 7 wherein said drape comprises an end portion connected to and closing one end of said cylindrical portion, said end portion being hemispherical.

B1 11. A system for providing a sterile field around an elongate body comprising an antimicrobial drape having a cylindrical portion and an end portion connected to and closing one end of said cylindrical portion, said end portion being hemispherical, said drape having sufficient flexibility to conform to at least a portion of an outer surface of the elongate body, said drape being puncturable to provide access to the outer surface of the body,

5 said drape being formed of expandable material and sized to have an internal volume which is less than the volume of the elongate body enabling said drape to be shrink-fitted onto the body, said drape being sterile to provide a sterile field around the  
10 outer surface of the body accessed by puncturing of said drape.

12. The sterile field system of claim 11 wherein said drape comprises plastic impregnated with iodophor.

15. The sterile field system of claim 11 wherein said drape is transparent to imaging radiation,

5 said sterile field system further comprising an indicia affixed to a portion of said drape, said indicia being opaque to the imaging radiation such that a radiographic image of the body resulting from passage of the image radiation through the body includes an indicia image corresponding to said indicia,

said shrink-fitting of said drape onto the body fixing said indicia relative to the outer surface such that said indicia provides a reference on said body for correlating portions of the body to the radiographic image thereof.

16. A system for providing a sterile field around a conical body comprising:  
a conical antimicrobial drape having sufficient flexibility to conform to at least a  
portion of an outer surface of the conical body, said drape having a longitudinally  
extending radial cutout comprising a base which coincides with a peripheral edge of said  
5 drape, said drape being puncturable to provide access to the outer surface of the body;  
and

means for fixing said drape to the outer surface of the body, said drape and fixing  
means being sterile to provide a sterile field around the outer surface of the body  
accessed by puncturing of said.

31  
17. The sterile field system of claim 16 wherein said drape comprises plastic  
impregnated with iodophor.

18. The sterile field system of claim 16 wherein said fixing means comprises  
adhesive applied to the surface of said drape which contacts the outer surface of the body.

20. The sterile field system of claim 16 wherein said drape is transparent to  
imaging radiation,  
said sterile field system further comprising an indicia affixed to a portion of said  
drape, said indicia being opaque to the imaging radiation such that a radiographic image  
5 of the body resulting from passage of the image radiation through the body includes an  
indicia image corresponding to said indicia,

said fixing means fixing said indicia relative to the outer surface such that said  
indicia provides a reference on said body for correlating portions of the body to the  
radiographic image thereof.

21. The sterile field system of claim 20 wherein said indicia comprises a system  
of polar coordinates having a center coinciding with the apex of said drape.

22. A method for correlating a selected portion within a body to a radiographic image of the body for treatment of the body, said method comprising the steps of:

applying a radio-transparent drape having radio-opaque indicia to the body;

fixing said drape and indicia to the body;

5 a first directing of imaging radiation through said drape and indicia such that a first radiographic image of said body and indicia is formed on a medium, the portion of the drape having the indicia which cause the formation of the indicia image defining an indicia region of the drape;

10 a first referencing on the radiographic image of the selected portion within the body relative to the indicia;

B1 a first locating of the selected portion within the body by referencing the body relative to the indicia on the drape in a manner corresponding to said first referencing of the radiographic image;

15 providing sufficiently unobstructed access to the indicia region of the drape to enable positioning by the hand of the operator adjacent to the indicia region of the drape; making a surgical incision through the indicia region of the drape and into the body sufficient to access the selected portion;

a second directing of imaging radiation through said drape and indicia such that a radiographic image of said body and indicia is formed on the medium;

20 a second referencing on the radiographic image of the selected portion within the body relative to the indicia; and

a second locating of the selected portion within the body by referencing the body relative to the indicia on the drape in a manner corresponding to said second referencing of the radiographic image.

23. The method of claim 22 wherein the step of making a surgical incision through the indicia region of the drape comprises placing of the hand of the operator in direct contact with the indicia region.



24. The method of claim 22 wherein said applying step comprises placing the drape on the body such that the body is disposed between at least two opposing portions of the indicia region of the drape, said placing of the drape further providing that each said portion of the indicia region of the drape is contained in a separate plane which is in  
5 parallel separation to the other plane.

25. The method of claim 24  
wherein said first or second referencing steps comprise identifying on the radiographic image the portions of the indicia intersected by an axis coinciding with a selected direction through the body, said axis being defined by intersections thereof with  
5 a specific indicia in each of said separate planes,

31  
said first or second locating steps comprising locating the selected direction through the body by referencing the body relative to the portions of the indicia on the drape identified in said corresponding referencing of the radiographic image.

26. A method for correlating a selected portion within a body to a radiographic image of the body for treatment of the body, said method comprising the steps of:

applying a radio-transparent drape having radio-opaque indicia to the body;  
fixing said drape and indicia to the body;

5 a first directing of imaging radiation through said drape and indicia such that a first radiographic image of said body and indicia is formed on a medium, the portion of the drape having the indicia which cause the formation of the indicia image defining an indicia region of the drape;

a first referencing on the radiographic image of the selected portion within the  
10 body relative to the indicia;

a first locating of the selected portion within the body by referencing the body relative to the indicia on the drape in a manner corresponding to said first referencing of the radiographic image;

providing sufficiently unobstructed access to the indicia region of the drape to  
15 enable positioning by the hand of the operator adjacent to the indicia region of the drape;  
making a surgical incision through the indicia region of the drape and into the  
body sufficient to access the selected portion within the body;  
inserting an implant through the surgical incision and into the body to the selected  
portion within the body;  
20 a second directing of imaging radiation through said drape and indicia such that a  
radiographic image of the body, indicia and implant is formed on the medium;  
a second referencing on the radiographic image of the implant and selected  
portion within the body relative to the indicia; and  
a second locating of the implant relative to the selected portion within the body by  
25 referencing the implant and body relative to the indicia on the drape in a manner  
corresponding to said second referencing of the radiographic image.

B1 27. A method for correlating a selected portion within and a selected direction  
through a body to a radiographic image of the body for treatment of the body, said  
method comprising the steps of:

5 applying a radio-transparent drape having radio-opaque indicia to the body;  
fixing said drape and indicia to the body;  
directing imaging radiation through said drape such that a radiographic image of  
said body and indicia is formed on a medium;  
referencing on the radiographic image the selected portion within the body  
relative to the indicia, said referencing step further comprising referencing a selected  
10 direction relative to the body and which intersects the selected portion, said referencing  
step comprising identifying a reference indicia defined by the indicia which is intersected  
by the selected direction;  
locating the selected portion of the body by referencing the body relative to the  
indicia on the drape in a manner corresponding to said referencing step of the  
15 radiographic image;

locating the selected direction by orienting a beam of light to coincide with the selected direction and to intersect the reference indicia;

positioning a surgical member adjacent to the drape such that the surgical member is intersected by the beam of light; and

20 translating the surgical member toward the drape such that the surgical member is continuously intersected by the beam of light, said translating step being over a sufficient length such that the surgical member passes through an opening in the drape and an incision in the body to become lodged within a portion of the body intersected by the selected direction.

28. A method for correlating the buttock with the femoral canal of the femur of a body, said method comprising the steps of:

B1  
5 applying a radio-transparent drape having at least two indicia each comprising a radio-opaque longitudinal axis to the leg of the body such that a first portion of the drape extends in an anterior-posterior plane relative to the body, said applying step further providing for a second portion of the drape to extend laterally relative to the body, said applying step providing further for each of the indicia to be contained in respective first and second portions of the drape, said applying step providing further for each of the indicia to be longitudinally and centrally aligned relative to the leg;

10 directing imaging radiation through said drape such that a radiographic image of said body and indicia is formed on a medium;

comparing, by viewing the radiographic image, the relative positions of each of the indicia relative to the longitudinal axis of the femoral canal;

15 translating the drape, as required, relative to the leg such that one of the indicia is contained in an anterior-posterior plane which coincides with the longitudinal axis of the femoral canal, and such that the other of the indicia is contained in a lateral plane which coincides with the longitudinal axis of the femoral canal; and

20 locating the intersection of the indicia on the buttock, the intersection of the  
indicia defining a start point for a reference axis which, when intersecting said start point  
and parallel to the indicia, coincides with the longitudinal axis of the femoral canal.

29. A method as set forth in claim 28 and further comprising the steps of:  
positioning a longitudinal nail relative to the leg such that a pointed end of the  
nail is adjacent to the start point on the buttock;

5 orienting the nail relative to the leg such that the longitudinal axis of the nail  
coincides with the reference axis;

inserting the nail through the tissue of the leg such that the longitudinal axis of the  
nail coincides with the reference axis, said inserting step being initiated by puncturing the  
outer surface of the leg at the start point with the pointed end of the nail;

10 inserting the nail further through the tissue such that the longitudinal axis of the  
nail continues to coincide with the reference axis, and such that the pointed end of the  
nail punctures the proximal end of the femoral canal; and

inserting the nail further into the femoral canal such that the longitudinal axis of  
the nail continues to coincide with the reference axis.